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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,026	02/05/2001	Orest W. Blaschuk	100086.402C1	6333

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EXAMINER
CLOW, LORI A

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 03/25/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/778,026	BLASCHUK ET AL.
	Examiner	Art Unit
	Lori A. Clow, Ph.D.	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 15 January 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 50 and 52-59 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 50 and 52-59 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .

4) Interview Summary (PTO-413) Paper No(s). _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

DETAILED ACTION

Applicant's election of Group V, claim 14, in Paper No. 14 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 20, 22-34, 36-49, 60-61, 63-68, and 189 and all other sequences are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected groups, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 14.

Claims 50 and 52-59 are pending in the instant application.

Information Disclosure Statement

The IDS, filed 23 November 2002 has been entered and partially considered. Portions of the IDS have been lined through and not considered because the references from the parent application, 08/939,853, now US 6,203,788, are not available. Applicant is requested to please provide copies of those references. An initialed copy of the form PTO-1449 is included with this office action.

Claims Rejections-35 USC 112

Claims 50 and 52-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) considered the issue of enablement in

molecular biology. The following eight factors were to be taken into account: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

- a) In order to practice the claimed invention one of skill in the art must treat cancer in a mammal by administration of a cell adhesion modulating agent. For the reasons below, this constitutes undue experimentation.
- b) and c) The specification provides a proposed use for the present invention in treating cancer. The specification states:

The formation of new capillaries is a prerequisite for tumor growth and the emergence of metastases. Administration of modulating agents as described herein **may** disrupt the growth of such blood vessels, thereby providing effective therapy for the cancer and/or inhibiting metastasis. Modulating agents may also be used to treat leukemias(page 48, lines 23-28).

This provides the only description of possible cancer treatment using said modulating agents. Nowhere else in the specification are specific examples given that indicate that these agents are used for treatment of a specific cancer. The specification provides no working examples of using a modulating agent in any cancer treatment methods. There is no indication in the specification as to how to use the disclosed modulating agents for treating all cancers.

- d) The invention is drawn to a method for treating cancer using a modulating agent.
- e) and g) The prior art teaches that significant testing must be implemented in order to establish a treatment for all cancers. In the instant case, the specification provides no indication

that the modulating agents are able to treat all cancers. Because there are no specific cancers, the experimentation contemplated would be undue.

f) The skill of those in the art of oncology is high, however it is known in the art that a particular agent or agents would not treat all cancers.

h) The claims are broad because they are drawn to treatment of cancer. However, there is no indication that the instant cell adhesion molecules are effective at treating any type of cancer or a specific cancer. Given the myriad of cancers and the myriad of causes, it is doubtful that the instant modulating agents would be successful at treating all types of cancers. For example, the modulating agents of the present invention are cell adhesion modulating agents. However, not all tissue types express all cell adhesion molecules. E-cadherin, for example, is predominantly expressed by epithelial cells (see Molecular Cell Biology (1995) Third Edition, Lodish et al., Eds., Scientific American Books, pages 1150-1155). Therefore, nothing in the specification would indicate that the said modulating agents are specific for every cell adhesion molecule that is expressed in every tissue type. Given the plethora of cancer types, the specification does not enable the use of said modulating agents to treat each and every type of cancer.

Furthermore, the specification presents examples of *in vitro* experimentation that are proposed to provide evidence of modulation of cell adhesion. However, one would question the extrapolation of this to actual *in vivo* treatment. The specification does not enable this type of use.

The skilled practitioner would first turn to the instant specification for guidance to practice methods of treating cancer, using cadherin modulating agents. However, the instant specification does not provide specific guidance to practice these embodiments. As such, the

skilled practitioner would turn to the prior art for such guidance, however, the prior art shows that such a use requires substantial experimentation on a variety of clinical samples, and is not predictable. Finally, said practitioner would turn to trial and error experimentation to determine the efficacy of using such agents. Such represents undue experimentation.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 10am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
GROUP 1600
1631

March 23, 2003

Lori A. Clow, Ph.D.
Art Unit 1631

Lori A. Clow